K081101

Implant Direct LLC
www.implantdirect.com

JAN 14 2009

Spectra-System Abutments 2008
Traditional 510(K) Submission

510(K) Summary (21CFR 807.92(a))

1. **Submitter's Information**
Company Name: Implant Direct LLC
Address: 27030 Malibu Hills Rd., Calabasas Hills, CA USA 91301
Telephone Number: 818-444-3300
Fax Number: 818-444-3400
Registration Number: 3001617766
Contact Person: Tom Gottenbos
Date Summary Prepared: March 13, 2008
Classification Name: Abutment, Implant, Dental, Endosseous
Common/Usual Name: Endosseous Dental Implant Abutment

2. **Device Trade Name:** Spectra-System Abutments 2008

3. **Predicate Device(s):** Implant Direct Spectra-System Dental Implant System (K061319), Sulzer Dental Screw-Vent Dental Implant System Custom Cast Abutments (K011028), Nobel Replace Tapered Groovy Custom Cast Abutments (K050258), Nobel Replace Tapered Groovy Multi Unit Abutments (K050258)

4. **Device Description:**
Spectra-System Abutments 2008 consist of a number abutment used in conjunction with dental implants for provisional, permanent or laboratory fabrication of a final dental prosthesis. The system includes Non-Engaging Titanium Temporary Abutments, Angled Screw-Receiving Abutments, Narrow ("N" Series) Abutments, Non-Engaging Plastic Abutments, Non-Engaging Gold Abutments and related components.

5. **Intended Use:**
The intended uses of the Spectra-System Abutments are identical to the intended use of the predicate implants. The included abutments are accessories to endosseous dental implants designed to support a prosthesis in the partially or fully endentulous mandible or maxilla. The laboratory components in this submission are used in a dental laboratory to aid in the fabrication of a final prosthetic appliance.

6. **Device Comparison:**
This submission is comprised of abutments whose physical dimensions, material composition, indications for use and methods of manufacture were previously approved and have the same principles of operation as the cited predicate devices. The differences between the components included in this submission and their predicate devise pose no new or additional issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Thomas Gottenbos
Vice President of IT / Regulatory Affairs
Implant Direct L.L.C.
27030 Malibu Hills Road
Calabasas Hills, California 91301

JAN 14 2009

Re: K081101
Trade/Device Name: Spectra-System Abutments 2008
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: December 22, 2008
Received: December 29, 2008

Dear Mr. Gottenbos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

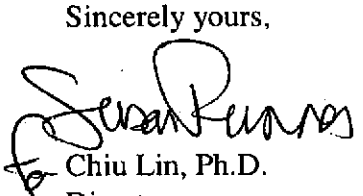
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081101

Device Name: Spectra-System Abutments 2008

Indications for Use:

Spectra-System Abutments are designed to be used in support of a dental implant(s) to provide support for prosthetic restorations such as crowns, bridges, overdentures or custom prosthetic fabrications in a partially or completely edentulous patient. Spectra-System Abutments are intended for use in the mandible or maxilla. Prostheses can be screw or cement retained to the abutment.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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